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10/510,005	08/12/2005	Ulrich Katscher	PHIDE020083US	9846
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FUJITA, KATRINA R				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/510,005

Applicant(s)

KATSCHER ET AL.

Examiner

KATRINA FUJITA

Art Unit

2624

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6 and 8-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6 and 8-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. This Office Action is responsive to Applicant's remarks received on December 01, 2008. Claims 2-6 and 8-14 remain pending.

Claim Objections

3. The following is a quotation of 37 CFR 1.75(a):

The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery.

4. Claim 5 is objected to under 37 CFR 1.75(a), as failing to particularly point out and distinctly claim the subject matter which application regards as his invention or discovery.

Claim 5 lacks antecedent basis for "the calculated image" in line 3. The following will be assumed for examination purposes: -- ~~the calculated image~~ an iteration image --.

5. The following is a quotation of 37 CFR 1.75(d):

The claim or claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.

6. Claim 5 is objected to under 37 CFR 1.75(d)(1), as failing to conform to the invention as set forth in the remainder of the specification.

Claim 5 requires "a difference between the first image data set and the iteration image data set" in line 5. While the initial iteration of the method will calculate the difference between first image data set and the iteration image data set due to the initialization of the iteration start image data set to the first image data set, subsequent iterations of the method calculate the difference between the new iteration start image data set and the iteration image data set as shown in Figure 3 and pages 7 and 8 of the specification. Therefore, the following will be assumed for examination purposes: -- a difference between ~~the first image data set~~ an iteration start image data set and the iteration image data set --. Further clarification and correction is required.

Claim Rejections - 35 USC § 112

7. The previous 112 rejection has been withdrawn in light of Applicant's amendment.
8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 6, 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For example, claim 6 recites "first tomographic image data acquisition means for the acquisition of a first image data set". However, in the specification at page 7, line 1, it is stated that the device comprises "SPECT image acquisition means M2" and is further silent about the specific structure of the SPECT image acquisition means. Likewise, the subsequent "means for" limitations lack descriptions of specific structure. Therefore, there is insufficient antecedent basis for the "means for" limitations of claim 6.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 6, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For example, claim 6 recites "first tomographic image data acquisition means for the acquisition of a first image data set". However, in the specification at page 7, line 1, it is stated that the device comprises "SPECT image acquisition means M2" and is further silent about the specific structure of the SPECT image acquisition means. Likewise, the subsequent "means for" limitations lack

descriptions of specific structure. As such, the Examiner is unable to determine the appropriate structure for performing the recited functions of the claim.

Claim Rejections - 35 USC § 101

12. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claims 2-5 and 10-12 are rejected under 35 U.S.C. 101 as not falling within one of the four statutory categories of invention. The Federal Circuit¹, relying upon Supreme Court precedent², has indicated that a statutory "process" under 35 U.S.C. 101 must (1) be tied to a particular machine or apparatus, or (2) transform a particular article to a different state or thing. This is referred to as the "machine or transformation test", whereby the recitation of a particular machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility (See *Benson*, 409 U.S. at 71-72), and the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity (See *Flook*, 437 U.S. at 590"). While the instant claim(s) recite a series of steps or acts to be performed, the claim(s) neither transform an article nor are positively tied to a particular

¹ *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008).

² *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).

machine that accomplishes the claimed method steps, and therefore do not qualify as a statutory process. That is, the “acquiring”, “reconstructing”, “forward projecting” and “associating” steps do not require machine involvement as currently claimed. Furthermore, the claims do not recite a qualifying transformation of data because there is no recitation of an external (non-data) representation of the physical object or substance, such as a visual depiction of the reconstructed image.

35 USC § 101

14. The method of claims 8 and 9 are shown to be successfully tied to a particular machine as the critical processing steps of “using a first tomography method” and “using a second tomography method” cannot be performed without a tomography apparatus.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipinski et al. ("Expectation Maximization", IEEE Article).

Regarding **claim 8**, Lipinski et al. discloses a method for selectively imaging body structures, comprising the steps of:

using a first tomography method to acquire a first image data set from a first spatial region ("PET images" at page 129, right column, line 13),

using a second tomography method to acquire a second image data set, the second tomography method having a higher resolution than the first tomography method ("images obtained by MRI" at page 129, right column, line 10) and the second image data set containing image data that at least partly coincides in space with image data of the first image data set (as seen in section E on page 131, the same Hoffman phantom was utilized for both tomography methods);

reconstructing the second image data set into a second image ("MR planes along the z-axis were summed, so that the resulting image comprised white and grey matter" at page 131, right column, line 11);

segmenting the second image to define a selected image region ("segmentation by thresholding" at page 131, right column, line 15);

segmenting the first image data set in accordance with the selected image region segmented from the second image to define a segmented first image data set ("observation of a relatively homogeneous tracer distribution within an MRI-defined tissue area can be included as *a priori* distribution in a statistically based PET reconstruction" at page 129, right column, second paragraph, last sentence);

reconstructing an image from the first image data set ("PET reconstruction" at page 129, right column, second paragraph, last sentence).

Regarding **claim 9**, Lipinski et al. discloses a method for selectively imaging body structures, the method comprising steps of:

using a first tomography method to acquire a first image data set ("PET images" at page 129, right column, line 13),

using a second tomography method to acquire a second image data set, the second tomography method having a higher resolution than the first tomography method ("images obtained by MRI" at page 129, right column, line 10) and the second image data set containing image data that at least partly coincides in space with image data of the first image data set (as seen in section E on page 131, the same Hoffman phantom was utilized for both tomography methods),

reconstructing an image from the first image data set ("PET reconstruction" at page 129, right column, second paragraph, last sentence), and

wherein data from the first image set used in the reconstruction set is selected using the second image data set; ("*a priori* information introduced in the iterative reconstruction procedure is derived from an MR image" at page 130, left column, section B, line 1),

wherein the reconstruction step further comprises the steps of:

selecting a region to be imaged from at least one region represented in the second image data set ("segmentation by thresholding" at page 131, right column, line 15), and

calculating the image reconstruction from image data in a region represented in the first image data set that corresponds to the selected region represented in the second data set ("observation of a relatively homogeneous tracer distribution within an MRI-defined tissue area can be included as *a priori* distribution in a statistically based PET reconstruction" at page 129, right column, second paragraph, last sentence).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 6, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipinski et al.

Regarding **claim 6**, Lipinski et al. discloses selective imaging of body structures, which includes

first tomographic image data acquisition means for the acquisition of a first image data set ("PET images" at page 129, right column, line 13),

second tomographic image data acquisition means for the acquisition of a second image data set, which second tomographic image data acquisition means have

a resolution which is higher than that of the first tomographic image data acquisition means ("images obtained by MRI" at page 129, right column, line 10),

backprojection means for image reconstruction of an image from the first image data set (Markov-GEM Algorithm at page 130, section C), and

selection means for selecting, by means of the second image data set, a portion of the first image data set to be reconstructed into a first tomographic image, wherein the portion of the first image data set is situated in a selected image region such that the backprojection means co-operate with the selection means in such a manner that the first tomographic image is calculated exclusively from the portion of the first image data set which are situated in the selected image region ("observation of a relatively homogeneous tracer distribution within an MRI-defined tissue area can be included as a *priori* distribution in a statistically based PET reconstruction" at page 129, right column, second paragraph, last sentence).

Lipinski et al. does not explicitly disclose a device that contains the above means that perform the functions.

However, it is well-known in the art to utilize a device, such as a computer, for reconstructions such as the one described above and therefore would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize a computer to accomplish the functions of the above reconstruction such that the reconstruction can be properly realized.

Regarding **claim 13**, Lipinski et al. discloses a device wherein the selecting means includes:

a segmenting means which segments a second image reconstructed from the second image data set ("segmentation by thresholding" at page 131, right column, line 15), the selected portion of the first image data corresponding to the segmented region of the second image ("observation of a relatively homogeneous tracer distribution within an MRI-defined tissue area can be included as a *priori* distribution in a statistically based PET reconstruction" at page 129, right column, second paragraph, last sentence).

Lipinski et al. does not explicitly disclose that the segmentation means is automatic.

However, it is well known in the art to utilize automatic segmentation routines to segment image data.

Therefore, it would have been obvious at the time the invention was made to employ an automatic segmentation means as the segmentation means of Lipinski et al. such that user input is unnecessary, thereby creating a more time efficient processing system.

Regarding **claim 14**, Lipinski et al. discloses a device further including:
registration means for registering the first image data set and the second image data set ("registration of MR and PET data" at page 133, section D, line 1).

19. Claims 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination Lipinski et al. and Ohba et al. (WO01/59477, utilizing corresponding US 7,191,109 as the translation).

Regarding **claim 10**, Lipinski et al. discloses a method of selecting imaging body structures comprising:

acquiring a first image data set from a first spatial region with a tomographic nuclear medical imaging technique ("PET images" at page 129, right column, line 13);

acquiring a second image data set from a second spatial region with a second tomographic imaging technique ("images obtained by MRI" at page 129, right column, line 10), the first and second spatial regions coinciding at least partially in space (as seen in section E on page 131, the same Hoffman phantom was utilized for both tomography methods);

reconstructing the second image data set into a second image ("MR planes along the z-axis were summed, so that the resulting image comprised white and grey matter" at page 131, right column, line 11);

segmenting the second image to define a segmented second image ("segmentation by thresholding" at page 131, right column, line 15);

reconstructing the segmented first image data set into a first image ("observation of a relatively homogeneous tracer distribution within an MRI-defined tissue area can be included as a *a priori* distribution in a statistically based PET reconstruction" at page 129, right column, second paragraph, last sentence ; "PET reconstruction" at page 129, right column, second paragraph, last sentence).

Lipinski et al. does not disclose forward projecting the segmented second image to form a segmented second image data set and associating the segmented second image data set with the first image data set to form a segmented first image data set.

Ohba et al. teaches a method of selecting imaging body structures comprising:
forward projecting the segmented second image to form a segmented second image data set ("forward projection of the mask image onto projection data is carried out, thus creating a projected mask" at col. 8, line 34); and

associating the segmented second image data set with the first image data set to form a segmented first image data set ("projected PET data (projected radiation data) and the projected mask are then composited" at col. 8, line 57; "projected PET data for the region of interest K is extracted" at col. 8, line 60).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the forward projection of Ohba et al. on the segmented MR data of Lipinski et al. to "improve the temporal resolution" (Ohba et al. at col. 9, line 20).

Regarding **claim 2**, Lipinski et al. discloses a method wherein the nuclear medical technique includes SPECT or PET ("PET images" at page 129, right column, line 13).

Regarding **claim 3**, Lipinski et al. discloses a method wherein the segmenting step is performed by a segmentation routine ("segmentation by thresholding" at page 131, right column, line 15).

Lipinski et al. does not explicitly disclose that the segmentation routine is automatic.

However, it is well known in the art to utilize automatic segmentation routines to segment image data.

Therefore, it would have been obvious at the time the invention was made to employ an automatic segmentation routine as the segmentation module of Lipinski et al. such that user input is unnecessary, thereby creating a more time efficient processing system.

Regarding **claim 4**, Lipinski et al. discloses a method wherein reconstructing the segmented first image data set is carried out by way of iterative backprojection (Markov-GEM Algorithm at page 130, section C; "iterative reconstruction" at page 130, section B, line 1).

Regarding **claim 12**, Lipinski et al. discloses a method further including:
reconstructing the first image data set into a first image ("PET reconstruction" at page 129, right column, second paragraph, last sentence);
registering the at least one of: the first and second images and the first and second image data sets ("registration of MR and PET data" at page 133, section D, line 1).

20. Claims 5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Lipinski et al. and Ohba et al. as applied to claim 4 above, and further in view of Wollenweber (US 6,590,213).

Regarding **claim 5**, Lipinski et al. discloses a method wherein the iterative backprojection includes:

numerically forming an iteration image data set from an iteration image (" $\lambda_i^{(n+1)}$ " at page 130, right column, equation 9),

determining a difference between an iteration start image data set and the iteration image data set (equation 9 on page 130 shows the difference at one iteration between $\lambda_i^{(n+1)}$ and the initial $\lambda_i^{(n)}$),

adding the difference to the segmented first image image ("uses the value of the last iteration step for λ " at page 130, right column, last sentence), and

iteratively repeating the above steps ("iterative reconstruction" at page 130, section B, line 1).

The Lipinski et al. and Ohba et al. combination does not disclose repeating the steps until at least one convergence criterion is satisfied.

Wollenweber teaches a method in the same field of endeavor of PET imaging comprising:

iteratively repeating the method steps until at least one convergence criterion is satisfied ("a value is recorded, each time when the step 152 is performed, that is indicative of the difference between a current overall value of the corrected, normal-sized (and tail-scaled) sinogram of step 150 and a previous overall value of that sinogram. Further, at step 152, if the difference falls below a certain level, then it is determined that the scatter estimation as been iteratively performed a sufficient number of times" at col. 8, line 66).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the convergence criterion of Wollenweber to terminate the iterations of the Lipinski et al. and Ohba et al. combination to avoid unnecessary

iteration processing after reaching a sufficient result and also avoid further addition of noise and artifacts that may arise as iterations continue past a certain point.

Regarding **claim 11**, Wollenweber discloses a method wherein the convergence criteria includes the difference dropping below a predetermined convergence value ("difference falls below a certain level" at col. 9, line 3).

Response to Arguments

21. Applicant's arguments with respect to claims 2-6 and 8-14 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATRINA FUJITA whose telephone number is (571)270-1574. The examiner can normally be reached on M-Th 8-5:30pm, F 8-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Werner can be reached on (571) 272-7401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katrina Fujita/
Examiner, Art Unit 2624
/Brian P. Werner/
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